**Conclusions:** A uniform and functionally active low-molecular weight heparin nanocoating was successfully combined with a RES TECHNOLOGY™ stent. This non-elutable heparin coating provided superior thrombosis resistance in two well-established aggressive models of stent thrombosis. The thromboresistant heparin nano-coating on a RES TECHNOLOGY™ stent may provide additional therapeutic benefits in complex lesions or in high risk patients.

## TCT-236

### A Prospective Multicenter Randomized Trial of PROSTENT Bioabsorbable Polymer vs. FIREBIRD Durable Polymer Sirolimus-Eluting Stent: 9-Month Angiographic and 12-Month Clinical Results

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**Background:** The biocompatibility of durable polymer used in the 1st generation drug-eluting stent was considered to one of the potential reasons for delaying endothelial healing and inducing very late stent thrombosis (VLST). Bioabsorbable polymer coating may potentially improve endothelial healing to decrease VLST. The aim of PROBE trial is to investigate the safety and efficacy of PROSTENT, an investigational device, which is a Co-Cr stent platform coated with PLGA bioabsorbable polymer with sirolimus.
**Methods:** PROBE was designed to be a multicenter randomized non-inferiority trial comparing PROSTENT (PS) vs. FIREBIRD (FB) durable polymer sirolimus-eluting stent. The primary endpoint was in-stent late loss at 9-month, secondary endpoints were binary restenosis, MACE (cardiac death, myocardial infarction (MI), or ischemia-driven TLR) at 1-year and stent thrombosis by ARC definition.
**Results:** 290 patients were enrolled from 17 sites. The patients were randomized into PS group (n=143) and FB group (n=147). The baseline characteristics were comparable between the two groups except more diabetics in FB than in PS group (20.4% vs. 11.9%, p=0.05). 9-month angiographic follow-up was completed in 244 cases (86.8%) and 1-year clinical follow-up completed in all cases. The in-stent late loss was 0.54±0.48mm in PS vs. 0.16±0.24mm in FB, the non-inferiority comparison was not met for the primary endpoint (diff., 0.40, 95%CI [0.30, 0.49], p<0.0001). The in-stent (7.5% vs. 0.6%, p=0.0006) and in-segment (8.8% vs. 2.4%, p=0.0105) binary restenosis rates were significantly higher in PS than that in FB group. At 1-year the composite of cardiac death or MI had a tendency to be higher in FB than in PS (6.2% vs. 1.5%, p=0.0521) and iTLR to be higher in PS than in FB (6.6% vs. 2.1%, p=0.0599), MACE and thrombosis were not significantly different between two groups (8.1% vs. 8.3%, p=0.8986; 0.7% vs. 1.4%, p=0.7119; respectively).
**Conclusion:** The non-inferiority comparison was not met for primary endpoint. The rates of MACE and thrombosis were no significant difference. The clinical efficacy and safety of PROSTENT were preliminarily confirmed by this randomized trial. (NCT 00887211)

## TCT-237

### NEVOTM Sirolimus-eluting Coronary Stent Attenuates Neointimal Formation and Inflammation in a Rabbit Atherosclerosis Vascular Injury Model

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**Background:** Sirolimus is an mTOR inhibitor that markedly reduces neointimal hyperplasia and inflammation. The NEVO™ Sirolimus-eluting Coronary Stent (SES) releases sirolimus from a bioabsorbable PLGA matrix using reservoirs (RES TECHNOLOGY™) instead of a conformal strut coating. In this study, we report the effect of NEVO™ SES on a rabbit model of atherosclerosis and vascular injury.
**Methods:** Male rabbits were placed on a proatherogenic high fat diet for 6 weeks. After 2 weeks of high fat diet, iliac arteries were denuded with a 4F balloon catheter and NEVO™ SES or control stents were implanted into the injured arteries under fluoroscopic guidance. After placement of stents, all animals received a continuous infusion of angiotensin II (60ng/kg/min) for 4 weeks via osmotic mini-pump to accelerate inflammation and lesion development. Four weeks after implant, animals were sacrificed and neointimal formation, vascular inflammation, and lipid deposition, were assessed in stented vessels using histomorphometry and immunocytochemistry.
**Results:** After 6 weeks of high fat diet, plasma cholesterol levels increased 45 fold (pre-high fat diet: 39.25 ± 1.68 mg/dL *vs* pre-necropsy: 1746.76 ± 121.81 mg/dL) (P<0.0001). Angiotensin II infusion induced marked inflammation in this model, as reflected by RAM11 staining. Compared to controls, NEVO™ SES significantly reduced neointimal area (NEVO™ SES: 1.22 ± 0.12 $mm^2$ *vs* control: 2.68 ± 0.26 $mm^2$, P<0.0001) and % area stenosis (NEVO™ SES: 22.06 ± 2.3% *vs* control: 50.76 ± 5.52%, P<0.0005). NEVO™ SES attenuated vascular lipid loading severity score (NEVO™ SES: 0.33 ± 0.13 *vs* control: 2.13 ± 0.24, P<0.0001) and neointimal foam cell score (NEVO™ SES: 0.77 ± 0.1 *vs* control: 2.07 ± 0.21, P<0.0001). NEVO™ SES markedly reduced macrophage infiltration based on RAM11 staining (positive stained pixels; NEVO™ SES: 16609 ± 6273 *vs* control: 424615 ± 118828, P<0.005). Smooth muscle cell alpha actin staining (pixel number) was reduced in the NEVO™ SES group, but not significantly (NEVO™ SES: 789486 ± 468428 *vs* Control: 928062 ± 461233, P>0.05).
**Conclusion:** Our data show that NEVO™ Sirolimus-eluting Coronary Stents dramatically reduce neointimal area (54.48% reduction), lipid deposition (84.51% reduction) and inflammatory cell infiltration in a rabbit model of atherosclerosis and provide mechanistic support for the beneficial effects of NEVO™ SES in patients with atherosclerotic vascular disease.

## TCT-238

### Four-Year Clinical Outcomes from the RESOLUTE First-In-Man Trial

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**Background:** Resolute is a zotarolimus-eluting stent (ZES), with a proprietary tripolymer coating (BioLinx®, Medtronic CardioVascular, Santa Rosa, CA) consisting of 1) the hydrophobic C10 polymer, which aids in the control of drug release; 2) the hydrophilic C19 polymer, which supports biocompatibility; and 3) polyvinyl pyrrolidinone, which increases the initial drug burst and enhances the elution rate. The hydrophilic surface mimics the body's biological chemistry, thereby reducing the risk of an inflammatory response. Resolute was tested in a first-in-human study of 130 patients from 12 centers in Australia and New Zealand. Four-year follow-up will be completed in August, 2010.
**Methods:** The RESOLUTE study enrolled symptomatic patients with single and multi-vessel coronary artery disease, but treated for only a single *de novo* lesion ≥ 14 mm and ≤ 27 mm in length, with a reference vessel diameter of ≥ 2.5 mm and ≤ 3.5 mm. Clinical follow-up is planned through 5 years.
**Results:** Baseline patient clinical characteristics include hyperlipidemia (94.6%), unstable angina (29.7%), prior MI (45.7%), and diabetes (17.7%). Of 131 lesions treated (2 lesions in 1 patient), mean length was 15.49±6.23 mm (range 4.36 -38.20), 82% were B2/C, and 46.2% of patients had multivessel disease. At 3 years, the cumulative incidence of TLR was 1.6%, TVF was 8.5%, MACE was 11.5%, and ARC definite and probable ST was 0.0%. Between year 1 and year 3, there was 1 TLR, 3 patients died of non-cardiac causes, 1 patient underwent a non-TL revascularization, but there were no MIs and no ARC ST events.
**Conclusions:** The Resolute ZES has shown long-term effectiveness and safety through 3-year follow-up with a TLR rate of 1.6% and an ARC definite and probable ST rate of 0.0%. We plan to report the 4-year clinical outcomes in September 2010.

## TCT-239

### OCT Evaluation At Baseline And 6 Months Follow-up Of The Self-expanding Nitinol Low-outward Force VShield Stent In Patients With Thin Cap Fibroatheroma In The Secritt Study (Shield Evaluated At Cardiac Hospital In Rotterdam For Investigation And Treatment Of TCFA)

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**Background**: vShield is a low outward force self-expanding nitinol device designed for treatment of the high risk thin cap fibroatheroma lesions (TCFAs). SECRITT study is a randomized single center pilot study of this device (n=15) versus medical therapy (n=15) in stabilizing TCFA.
**Methods**: 9 of the 14 patients randomized to vShield treatment underwent baseline and 6 month follow-up evaluation with optical coherence tomography (OCT). Cross-sections within the stented region and the proximal and distal edges (5mm) were analyzed at 1 mm intervals. Apposition was quantitatively assessed strut by strut at baseline and follow-up. Tissue coverage was assessed per-strut only at follow-up. Areas, volumes, dissection flaps and intraluminal filling defects were also analyzed. Two independent observers performed the measurements and the results were adjudicated by a third experienced reader.
**Results**: A total of 11 stents were evaluated at baseline (two patients had two overlapping vShields implanted). Total length of stents evaluated at baseline was 127.15 mm, including two overlap regions. Mean lumen area was 9.03±2.29 mm2 and mean stent area was 8.67±2.16 mm2. In two patients there was high degree of malaposition due to undersizing of the device. Mean ISA area was 0.36±0.47 mm2. Mean prolapse area was 0.009±0.17 mm2. of the 1,721 stent struts counted at baseline 1,521 were well apposed, 185 (10.7%) were malapposed and 15 were in front of side branches. There were no dissections seen. Mean thrombus area was 0.015 mm2. At 6 month follow up 12 stents were evaluated with a total length of 142.95 mm. Mean lumen area was 8.36±2.87 mm2 (decreased by 7.4%), with late loss of 0.13 mm. There were no binary restenosis events. Mean stent area increased to 9.45±2.30 mm2 (by 8.9%), implying continued stent expansion. Mean ISA area was 0.88±0.85 mm2. Of the total of 2072 struts evaluated, 1910 were well apposed, 159 were malapposed (7.6%; decrease from baseline), and 3 were in font of a side-branch. 8.1% of all struts were non-covered. Of the well-apposed struts 93.2% were covered, while of the malapposed struts 78% were covered.
**Conclusion**: vShield device causes minimal dissections and vessel wall trauma. It continues to expand by 8.9% over 6 months such that number of malapposed struts decreases overtime. 8.1% of struts remain uncovered similarly to some of the drug eluting stents.

## TCT-240

### PLATINUM QCA: A Prospective, Multicenter Trial Assessing Clinical, Angiographic, and Intravascular Ultrasound Outcomes (9 Months) with the Novel Platinum-Chromium Thin-Strut PROMUS Element Everolimus-Eluting Stent in De Novo Coronary Stenoses

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**Background:** Everolimus-eluting stents (EES) reduce restenosis following percutaneous coronary intervention as compared to earlier generation paclitaxel-eluting stents (PES). The next generation PROMUS Element EES (Boston Scientific Corporation, Natick, MA, USA) consists of a novel platinum-chromium alloy thin-strut radiopaque stent with improved radial strength and low recoil. We report for the first time results of the PLATINUM QCA trial which collected clinical outcomes, quantitative coronary angiography (QCA) data, and intravascular ultrasound (IVUS) data in lesions treated with PROMUS Element.
**Methods:** Subjects with a *de novo* target lesion length ≤34 mm in a vessel of ≥2.25 mm to <4.25 mm diameter were treated in this prospective, single-arm, multicenter trial. The primary endpoint was the 30-day composite rate of cardiac death, myocardial infarction (MI), target lesion revascularization (TLR), and definite or probable stent thrombosis (ST). The efficacy endpoint of 9-month in-stent late loss by QCA was compared to a prespecified performance goal based on historical results with TAXUS Express PES. Additional endpoints include 9-month percent diameter stenosis and binary restenosis (QCA); 9-month percent net volume obstruction and incomplete apposition (IVUS); and clinical endpoints of all-cause death, cardiac death, MI, revascularization, and ST at 9 and 12 months.
**Results:** Subjects (n=100) were enrolled at 14 clinical sites in Australia, New Zealand, Malaysia, and Singapore. Mean age was 62 years, 23% of patients were female, and 19% of patients had medically treated diabetes mellitus. Lesions treated were in the left anterior descending (35%), the left circumflex (30%), and the right coronary (35%) arteries. Technical success (successful study stent delivery and deployment to the target lesion without balloon rupture or embolization) was 100% (108/108). Clinical procedural success (mean lesion diameter stenosis <30% with TIMI 3 flow and no in-hospital cardiac death, MI, or revascularization) was 99% (99/100). One patient (1.0%) had a periprocedural ST resulting in a TLR. There were no other major clinical events from discharge through 30 days.

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